IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados,	)	
Plaintiff,	)	C.A. No. 05-586-GMS
	)	C.A. No. 05-730-GMS
v.	)	C.A. No. 06-620-GMS
	)	CONSOLIDATED
ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION	)	**PUBLIC VERSION**
Defendants.	)	

FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

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Dated: March 20, 2007
Public Version Dated: March 27, 2007
785858 / 30015

Defendants, Andrx Pharmaceuticals, LLC and Andrx Corporation (hereinafter "Andrx"), by its attorneys, answer the Complaint herein as follows:

1. Andrx denies that there is information sufficient to form a belief as to the allegations contained in paragraph 1 of the Complaint.

2. Andrx admits the allegations contained in paragraph 2 of the Complaint.

3. Andrx admits the allegations contained in paragraph 3 of the Complaint.

4. Andrx admits the allegations contained in paragraph 4 of the Complaint.

5. Andrx admits the allegations contained in paragraph 5 of the Complaint.

6. Andrx admits that this action arises under the patent laws of the United States of America and specifically under 35 U.S.C. § 271(e) and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Andrx denies the remaining allegations contained in paragraph 6 of the Complaint.

7. Andrx admits the allegations contained in paragraph 7 of the Complaint.

8. Andrx admits that it manufactures pharmaceutical products that are sold and used, including through subsidiaries, throughout the United States, including this District. Andrx denies that it manufactures bulk pharmaceuticals.

9. Andrx repeats the admissions and denials of paragraphs 1-8 above in response to the allegations in paragraph 9 of the Complaint.

10. To the extent that Paragraph 10 of the Complaint states conclusions of law, Andrx states that no response is required. To the extent that Paragraph 10 of the Complaint states allegations of fact, Andrx admits that United States Patent No. 7,108,866 ("the '886 patent") was issued on September 19, 2006 to Biovail, which is listed on the patent as the assignee of the named inventors, Kenneth Stephen Albert and Paul Jose Maes.

11. Andrx admits the allegations contained in paragraph 11 of the Complaint.

12. Andrx denies that there is information sufficient to form a belief as to the allegations contained in paragraph 12 of the Complaint.

13. Andrx admits the allegations contained in paragraph 13 of the Complaint.

14. Andrx admits the allegations contained in paragraph 14 of the Complaint, except is without information sufficient to form a belief as to the allegation as to when Biovail received the notice letter.

15. Andrx denies the allegations in paragraph 15 of the Complaint.

16. Andrx denies the allegations in paragraph 16 of the Complaint.

17. Andrx denies the allegations in paragraph 17 of the Complaint.

18. Andrx denies the allegations in paragraph 18 of the Complaint.

FIRST DEFENSE

19. Upon information and belief, Andrx has not infringed any valid and enforceable claim of the '866 patent.

SECOND DEFENSE

20. Upon information and belief, Andrx alleges that the '866 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 102, 35 U.S.C. § 103, or 35 U.S.C. § 112.

THIRD DEFENSE

21. Upon information and belief, Andrx alleges that the claims of the '866 patent are unenforceable due to inequitable conduct by the applicants and/or the applicants' attorneys before the United States Patent and Trademark Office ("PTO")

during prosecution of the '866 patent in violation of the duties imposed by 37 C.F.R. § 1.56 ("Rule 56").

22. Rule 56 imposes a duty of candor and good faith upon each individual associated with the filing and prosecution of a patent application in dealing with the PTO. That duty includes an affirmative obligation to disclose to the PTO all material information known to those individuals associated with the filing and prosecution of a patent application.

23. Material information under Rule 56 includes, but is not limited to, information which refutes or is inconsistent with a position the patent applicants take in asserting an argument of patentability or opposing an argument of unpatentability relied upon by the PTO.

24. The obligations and requirements of Rule 56 applied to those individuals associated with the filing and prosecution of the patent applications that ultimately led to the issuance of the '866 patent, including the named inventors of the applications that ultimately led to the issuance of the '866 patent, the attorneys involved in drafting and/or prosecuting the applications that ultimately led to the issuance of the '866 patent, and every other person who was substantively involved in the preparation or prosecution of the patent applications that ultimately led to the issuance of the '866 patent.

25. Upon information and belief, the '866 patent issued from a patent application filed on May 8, 2000, numbered 09/567,451 ("the '451 application"). The '451 application was a continuation-in-part application of another patent application filed on December 17, 1999, numbered 09/465,338 ("the '338 application").

26. During the prosecution of the patent applications that ultimately led to the issuance of the '866 patent, the applicants and their attorneys of record engaged in a pattern of misconduct designed to secure the issuance of the '866 patent. That pattern of misconduct included misrepresentations as to properties of prior art formulations, submission of a false and misleading expert affidavit, withholding contrary experimental data, withholding material prior art, and misleading representations as to the operability of alternative pharmaceutical formulations without experimental basis.

MISREPRESENTATION OF PRIOR ART FORMULATIONS

27. During prosecution of the '451 application, in order to overcome prior art rejections, applicants through their attorney, Robin Teskin, represented to the PTO in an amendment of January 3, 2006, on page 32 that "all of the cited prior art relating to diltiazem formulations possess T_{max} times (the times at which diltiazem levels in the serum (C_{max}) are at their highest) which occurs about 6 hours after administration." (Exhibit A, at p. 32.)

28. Among the cited prior art referred to in Teskin's representation is European Patent Application Number 0 856 313 (hereinafter "Geoghegan '313 Application"). (Exhibit B.) Another cited prior art reference referred to in Teskin's representation is International Patent Publication Number WO 93/00093 (hereinafter "Deboeck '093 Publication"). (Exhibit C.)

29. Teskin, on behalf of the applicants in the same Amendment, further represented specifically with reference to the Geoghegan '313 Application, that "Geoghegan completely fails to teach or suggest a diltiazem formulation which attains C_{max} at a time between 10-15 hours after administration." (Ex. A, at p. 35.)

30. Teskin's representations to the PTO were false and misleading.

31. The Geoghegan '313 Application expressly teaches a diltiazem formulations which attain C_{max} at times between 10-15 hours after administration. For example, one diltiazem formulation attained a T_{max} at 14.00 hours as reported in the Geoghegan '313 Application. (Ex. B, at p. 20 ("However, the main distinguishing feature is the tmax (time to peak plasma levels) which is considered to be the single most important pharmacokinetic criterion for characterizing a specific dosage frequency. The tmax for the formulation in Example 1 is 14.00 hours, thus indicating suitability thereof for once-daily administration. . . .").) A second diltiazem formulation attained a T_{max} of 13.20 hours as reported in the Geoghegan '313 Application. (Ex. B, at p. 22 ("The formulation of Example 2 attained a remarkably extended tmax of 13.20 hours after administration. . . .").)

32. Similarly, the Deboeck '093 Publication expressly teaches a diltiazem formulation with a T_{max} of 8.0 hours, in direct contradiction to Teskin's affirmative representation that all cited prior art diltiazem formulations have a T_{max} at about 6 hours. (Ex. C, at p. 16, Figure 1.)

33. The misrepresentations submitted to the PTO were submitted with an intent to deceive the PTO.

THE FALSE AND MISLEADING "EXPERT" DECLARATION

34. During prosecution of the '451 application, applicants, through their attorney, Teskin, submitted an affidavit of one Edith Mathiowitz, Ph.D.

35. Applicants, through their attorney, Teskin, at page 42 of a document entitled "Reply, Amendments and Submission of Affidavit by Edith Mathiowitz, Ph.D.

and Exhibits" dated April 11, 2005, represented to the PTO that Mathiowitz was a "renowned expert in sustained drug delivery systems." (Exhibit D, at p. 42.)

36. Mathiowitz, in paragraph 3 of her affidavit dated April 10, 2005, represented under oath to the PTO that she was "well qualified to give an opinion concerning the subject matter that is claimed in the above-identified patent application [the '451 application]. . . ." (Exhibit E, at ¶ 3.)

37. Mathiowitz represented that she had reviewed various materials, including the Geoghegan '313 Application and the Deboeck '093 Publication. (Ex. E, at ¶ 10.) Mathiowitz represented that she reviewed testing relating to a formulation (referred to by Mathiowitz as Diltiazem LA) corresponding to the claims being pursued in the '451 application. (Ex. E, at ¶ 13.) Mathiowitz further represented that she reviewed additional testing conducted on Cardizem CD and Tiazac, which correspond to the Geoghegan '313 Application and the Deboeck '093 Publication, respectively. (*Id.*)

38. Mathiowitz also represented that she reviewed a published clinical study relating to the diltiazem formulation being claimed by Biovail in the patent applications at issue. (Ex. E, at ¶ 14.)

39. Mathiowitz represented to the PTO that the claims of the '451 application would cover, among other things, diltiazem compositions where "(i) Cmax occurs about between 10 and 15 hours after ***evening*** administration . . . ." (Ex. E, at ¶ 17 (emphasis added).)

40. Mathiowitz's representation was false and misleading.

41. The sample claim provided at paragraph 16 of the Mathiowitz Affidavit plainly states that the formulation must provide "a Cmax of diltiazem in the blood at

between about 10 and 15 hours after ***oral*** administration." (Ex. E, at ¶ 16 (emphasis added).) Under PTO regulations, the PTO must consider the claims under the broadest possible claim construction. The time of C_{max} according to the claim described in paragraph 16 of the affidavit is to be measured following ***oral*** administration, not ***evening*** administration, as Mathiowitz misleadingly presented to the PTO.

42. Mathiowitz intended to deceive the PTO by using her sleight of hand on the issue of claim scope to misrepresent the properties of prior art formulations. Mathiowitz attached at Exhibit 6 to her declaration data purporting to show a 6 hour T_{max} for Cardizem CD (which corresponds to the Geoghegan '313 Application) when dosed in the ***evening***. A true and correct copy of Exhibit 6 to the Mathiowitz Affidavit is attached hereto as Exhibit F. Similarly, Mathiowitz attached at Exhibit 7 to her declaration data purporting to show a 6 hour T_{max} for Tiazac (which corresponds to the Deboeck '093 Publication) when dosed in the ***evening***. (Exhibit G.)

43. Under the plain language of the claim as set forth in the Mathiowitz Affidavit at paragraph 16, the T_{max} is to be 10 to 15 hours after ***oral*** administration. As described above, the Geoghegan '313 Application teaches at least two exemplary formulations wherein the T_{max} is within the range of 10 to 15 hours.

44. Throughout her affidavit, Mathiowitz misleadingly states that the T_{max} of the prior art formulations differs from the claimed Diltiazem LA after ***evening*** administration. (*See, e.g.*, Ex. E, at ¶¶ 21, 22, 23, 24, 25, 27, 31, 37, and 38.)

45. Despite holding Mathiowitz out as an expert to the PTO regarding the claimed subject matter, Mathiowitz failed to consider or inform the PTO of T_{max} values

between 10 to 15 hours following administration expressly taught in the Geoghegan '313 Application.

APPLICANTS WITHHELD CONTRARY EXPERIMENTAL DATA

46. While applicants through their attorney, Teskin, and through their "expert" Mathiowitz provided the PTO with testing that purported to show T_{max} of about 6 hours for Cardizem CD (corresponding to the Geoghegan '313 Application), applicants had in their possession internal Biovail testing that showed [redacted] This contradictory internal testing was never disclosed or revealed to the PTO in violation of the applicants' duty of candor and good faith to the PTO.

47. For example, at page [redacted] of an internal Biovail report dated [redacted] relating to [redacted] demonstrated [redacted] (Exhibit H, at [redacted])

48. Applicants were aware of the results of the Exhibit H study prior to the filing of the '451 application. In fact, the mean pharmacokinetic parameters and mean plasma diltiazem concentrations reported [redacted] are taken directly from the study report at Exhibit H, at pages [redacted] However, the corresponding values for [redacted] (including the determination of the [redacted]) were deliberately not included in the '866 patent, and were intentionally not disclosed to the PTO by the applicants in violation of the duty of candor and good faith to the PTO. This deliberate non-disclosure of contradictory experimental results was a material omission, and was intended to deceive the PTO.

49. Similarly, an internal Biovail [redacted] reports data from a comparison of

[redacted] and [redacted]. (Exhibit I.) The results for [redacted] at page [redacted] show [redacted] (Ex. I, at p. [redacted]) Similarly, the same report shows in yet another study of [redacted] (Ex. I, at p. [redacted]) [redacted] testified at deposition in this action that he was aware of this [redacted]

50. Applicants, including [redacted] deliberately withheld the contradictory testing information contained in this report relating to [redacted] prior art (including the [redacted] information) from the PTO in violation of their duty of candor and good faith to the PTO.

APPLICANTS WITHHELD MATERIAL PRIOR ART

51. Similarly, the United States Food and Drug Administration ("FDA") approved marketing the Cardizem CD product in 1991. As part of that approval, a package insert based upon clinical data was approved to accompany the Cardizem CD product. The substance of these package inserts are collected and published in the Physicians' Desk Reference (hereinafter "PDR"). (Exhibit J (excerpts from 1994 PDR).)

52. Exhibit J constitutes prior art to the '866 patent.

53. Exhibit J provides that Cardizem CD had "peak plasma levels between 10 and 14 hours . . . ." (Ex. J, at page 1295.) This data squarely contradicts the data relating to Cardizem CD submitted to the PTO.

54. Applicants were aware of Cardizem CD, and its status as prior art. Teskin was aware of Cardizem CD, and its status as prior art. Mathiowitz was aware of Cardizem CD, and its status as prior art. Each of these individuals owed a duty of candor and good faith to the PTO. None of these individuals disclosed Exhibit J to the PTO, in

violation of their duties of candor and good faith to the PTO. The failure to disclose Exhibit J was intended to deceive the PTO.

55. In her Affidavit, Mathiowitz represents that the recited *in vivo* properties "render the Biovail diltiazem formulations exquisitely suited for chronotherapeutic use." (Ex. E, at ¶ 17.) Mathiowitz further represented under oath to the PTO that "the prior art does not suggest diltiazem compositions have the advantageous properties of the Biovail compositions . . ." referring, at least in part, to chronotherapeutic use.

56. Mathiowitz's representation was false. Biovail itself publicly announced more than one year prior to the filing of the '451 application that "[f]rom a chronotherapeutic perspective, this new once-a-day capsule formulation [Tiazac] may offer an advantage over other such diltiazem products in the treatment of hypertension." (Exhibit K, at 373.) Indeed, On information and belief, applicants including Maes were aware of this publication at the time the '451 application was filed.

57. Despite this clear prior art reference to chronotherapeutic use of prior art Tiazac by Biovail, neither Maes, nor Mathiowitz, nor Teskin, nor any individual involved in the prosecution of the '451 application disclosed this material prior art reference to the PTO. This violated the duty of candor and good faith these individuals owed to the PTO. This material prior art reference was withheld from the PTO with an intent to deceive the PTO.

MISREPRESENTATIONS OF OPERABILITY OF ALTERNATIVE PHARMACEUTICAL FORMULATIONS

58. During an interview with the PTO in an attempt to obtain approval of the claims, "Dr. Maes further explained that based on this surprising discovery, the preparation of other chronotherapeutic diltiazem formulations possessing the claimed

properties, can be achieved by the use of other commercially available water insoluble swellable neutral copolymers, *e.g.,* Kollicoat® 'SR 30 D, (a polyvinyl acetate neutral copolymer sold by BASF for use in sustained release coating formulations, protective coatings, and sustained-release matrix formulations)." (Ex. D, at 38.)

59. Maes' representations to the PTO were further adopted and repeated by Teskin, attorney for Biovail, in a document filed with the PTO entitled "Reply, Amendments And Submission of Affidavit By Edith Mathiowitz, Ph.D. And Exhibits" dated April 11, 2005. (*Id.*)

60. On information and belief, at the time Maes made this representation to the PTO, neither Maes nor any other person at Biovail had ever made and tested a chronotherapeutic diltiazem formulation containing the above-referenced Kollicoat that possessed the claimed properties. On information and belief, at the time Maes made these representations to the PTO, Maes knew that no testing of any such chronotherapeutic diltiazem formulation containing Kollicoat had been conducted. On information and belief, Maes was the leader of the pharmaceutical team at Biovail on the development of Biovail's Cardizem LA product, and had knowledge in that capacity of the testing and making of diltiazem-containing pharmaceutical formulations at Biovail.

61. At the time Maes made that representation to the PTO, Maes knew that his representation to the PTO was false and/or misleading.

62. On information and belief, Maes intended to deceive the PTO in order to achieve allowance of what ultimately issued as the '866 patent.

63. Teskin reiterated Maes' remarks in the Amendment, and was under a duty of candor and good faith to the PTO. By reiterating these remarks without determining if

any such testing had occurred, Teskin violated her duties to the PTO. Teskin intended to deceive the PTO.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Andrx counterclaims against Plaintiff, Biovail Laboratories International SRL, for declaratory relief and alleges:

64. Subject matter jurisdiction for this counterclaim for declaratory judgment is based upon 28 U.S.C. §§ 1338, 2201, and 2202 and Rule 13 of the Federal Rules of Civil Procedure. An actual case or controversy exists between Biovail and Andrx based upon Biovail having filed this complaint against Andrx.

COUNT I

65. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-64 of this Answer.

66. Andrx is entitled to a judgment declaring that it has not infringed any valid and enforceable claim of the '866 patent.

COUNT II

67. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-64 of this Answer.

68. Andrx is entitled to a judgment declaring that the '866 patent is invalid for failure to comply with one or more of the requirements for patentability in one or more of 35 U.S.C. § 102, 35 U.S.C. § 103, or 35 U.S.C. § 112.

COUNT III

69. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-64 of this Answer.

70. Andrx is entitled to a judgment declaring that the '866 patent is unenforceable due to inequitable conduct.

COUNT IV

71. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-64 of this Answer.

72. Biovail's allegations of infringement are wholly unjustified, and, on information and belief, were asserted for the improper purpose of delaying the entry of Andrx's proposed generic product, which will compete with Biovail's diltiazem product. The case should be deemed "exceptional" under 35 U.S.C. § 285. Andrx is entitled to the relief provided by 35 U.S.C. § 285, including attorney fees as a result of Biovail's actions.

WHEREFORE, Andrx demands:

A. That the Complaint filed herein be dismissed and that the Plaintiff have and recover nothing by reason thereof;

B. that United States Patent No. 7,108,866 be declared and adjudged invalid;

C. that United States Patent No. 7,108,866 be declared and adjudged unenforceable;

D. that it be declared and adjudged that Andrx has not infringed and will not infringe any valid and enforceable claim of United States Patent No. 7,108,866;

E. that this case be adjudged and decreed an exceptional case under 35 U.S.C. § 285 and that Andrx be entitled to recover reasonable attorneys' fees and costs incurred in this action;

F. that Andrx be awarded damages, including punitive damages, for the assertion of a patent which Counterclaim Defendant knew to be invalid and/or unenforceable;

G. such other and further relief as the Court deems just and equitable.

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